MAR - 1 2001

K003059
1 of 3

510 (K) Summary

Exhibit C

Pride Mobility Products, Corp.
510 (K) Premarket Notification
Laser 4

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Pride Mobility Products, Inc.
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-4849

Contact Person: Gene Kulon
Official Correspondent
Date Prepared: 05-15-00

Name of Device and Name / Address of Sponsor:

Laser 4

Pride Mobility Products, Inc.
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-4849

Common or Usual Name:
4-wheeled scooter

Classification Name:
Vehicle, Motorized 3-wheeled

Comparison to Predicate Devices:

The Laser 4 is a Legend SC-340 that has been enhanced by altering the plastic shrouds to a more state of the art look. Fir added safety turn signals, taillights and headlight package is now standard equipment. An additional safety feature has been added called Speed Control Technology (SCT) that consists of a turbo button, turning sensors and mercury tilt sensors. The SCT turbo button will allow the patient additional speed only on a flat and strait away path up to 8mph. When in Turbo the unit will slow during turns and additionally it will slow down on hills, both sideways and forward down. All safety features are equivalent or better on the Laser 4.
Device Description:

Another major innovation introduced with the Laser Sport Scooter is our exclusive patent pending Scooter Control Technology (SCT). SCT senses incline conditions and vehicle directional orientation to automatically disable the 'turbo" mode during cornering, in steep descents or in extreme lateral banking. This provides the user with added confidence in knowing that his/her driving skills are supplemented by a state-of-the- art system to safeguard against excessive speed in situations that require greater caution.

NOTE: The additional margin of safety provided by SCT should only be considered a supplement to safe driving habits and thorough practice in operating the Scooter in strict compliance with all conditions outlined in the owner's manual.

Section 5 - Comparison to the 510(k) Cleared Device

The Laser 4 is a Legend SC-340 that has been enhanced by altering the plastic shrouds to a more state of the art look. Turn signals, taillights and headlight package is now standard equipment. A safety feature has been added called Speed Control Technology (SCT) that consists of a turbo button, turning sensors and mercury tilt sensors. The SCT turbo button will allow the patient additional speed on a flat and strait away path only. When in Turbo the unit will slow down during turns and additionally the scooter will slow down on hills, both sideways and forward down.

Section 6 - Proposed Labeling for the Device

Identify all changes in the proposed labeling that may result from modification to your legally marketed device.

Labeling to be the same as the cleared device except for the following:

Laser model decals: Exhibit D

Owners Manual: Exhibit E

Section 7 - Summary of Design Control Activities, (21) CFR Part 807.87 (g):

a. Identification of the Risk Analysis Method (s) used to Assess the Impact of the Modification on the device and it's components as well as the results of the analysis: Exhibit F

b. Based on the Risk Analysis, an identification of the Verification and/or Validation Activities required, including Methods or Tests Used and the Acceptance Criteria Applied: Exhibit G

c. Declaration of Conformity with Design Controls:

Statement/Certification #1

As required by the risk analysis performed in Section 7(a) and (b) above, all verification and validation activities were performed by the designated individual (s) identified in the Risk Analysis Protocol, and, the results demonstrated that the pre-determined acceptance criteria were met.

Please refer to Exhibit H for a copy of this signed statement by the designated individual(s) responsible for this particular activity.

Statement/Certification #2

Jim Mulhern certifies that our manufacturing facility, located at 182 Susquehanna Avenue, Exeter, PA 18643, is in conformance with the design control procedure requirements as specified in 21 CFR Part 820.30 and the records are available for review.

Please refer to Exhibit I for a copy of this signed statement by the designated individual(s) responsible for this particular activity.

Statement/Certification #3

The fundamental scientific technology of the modified device (Laser 4) has not changed from that of the original device (Legend SC-340). Please refer to Exhibit J

Additional Information: Quality Assurance and Manufacturing Controls:

Pride Mobility Products, Corporation operates in compliance with FDA's Good Manufacturing Practice Regulations for Medical Devices (21 CFR Part 820), and, a formally established and controlled Quality Assurance Program. Devices are manufactured and assembled to established and controlled device master record requirements by formally trained and supervised personnel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Mr. Gene Kulon
Official Correspondent
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

Re: K003059
Trade Name: Laser 4SPSC340
Regulatory Class: II
Product Code: INI
Dated: December 19, 2000
Received: December 28, 2000

Dear Mr. Kulon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT B

510(k) Number (if known): K003059

Device Name: Laser 4, SPSC340, 4-wheeled scooter

Indications For Use:

The Laser 4 has been designed to help people who have a difficult time walking. The patient must have use of hands and some upper body mobility. People who have some mobility, but cannot walk for long distances or people that may need crutches to walk will generally purchase this scooter. The Laser 4 is designed for both indoors and limited outdoor use to clean and dry conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **(Per 21 CFR 801.109)** **OR** Over-The-Counter Use ____ **(Optional Format 1-2-96)**

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003059